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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/782,745	02/13/2001	Pierre van der Bruggen	LUD-5531.1 DIV	7125

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EXAMINER	
DIBRINO, MARIANNE NMN	
ART UNIT	PAPER NUMBER
1644	17

DATE MAILED: 04/16/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

PTO-90C (Rev. 07-01)

Office Action Summary	Application No.	Applicant(s)
	09/782,745	BRUGGEN ET AL.
	Examiner	Art Unit
	DiBrino Marianne	1644

-- *The MAILING DATE of this communication appears on the cover sheet with the correspondence address* --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *30 October 2002*.

2a)☒ This action is **FINAL.** 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *41-50* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *49 and 50* is/are rejected.

7)☒ Claim(s) *41-48* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *08 May 2001* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

1. Applicant's amendment filed 10/30/02 (Paper No. 14) is acknowledged and has been entered.

2. Applicant is reminded of Applicant's election with traverse of Group I (claims 32-40), the isolated nucleic acid molecule (SEQ ID NO: 14) encoding GAGE-2 protein (SEQ ID NO: 27) and the species of HLA molecule HLA-Cw6 in Applicant's response filed 5/22/02.

Claims 41-50 are pending and are being acted upon presently as they pertain to SEQ ID NO: 14 and HLA-Cw6.

3. The proposed drawing correction filed on 5/8/01 has been disapproved because it is not in the form of a pen-and-ink sketch showing changes in red ink or with the changes otherwise highlighted. See MPEP § 608.02(v).

In view of Applicant's amendment filed 10/30/02, the following objection remains.

4. The disclosure is objected to because of the following informalities:

a. The Brief Description of the Drawings should be amended from "Figure 1" to --Figure 1 A-D--, "Figure 4" to --Figure 4A-D--.

b. The disclosure is objected to because it contains an embedded hyperlink and/or other form of browser-executable code on page 26 at line 2. Applicant is required to delete the embedded hyperlink and/or other form of browser-executable code. See MPEP § 608.01.

Appropriate corrections are required.

The following are new grounds of rejection necessitated by Applicant's amendment filed 10/30/02.

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Claim 49 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new matter rejection.

The amendatory material not supported by the specification and claims as originally filed is: "An isolated nucleic acid molecule which encodes a GAGE tumor rejection antigen precursor, the complementary sequence of which hybridizes, at the following conditions:...".

Applicant points to support for claim 49 on page 28 of the replacement specification at lines 8-12. The disclosure at the said location in the specification is for the definition of stringent conditions. The disclosure immediately preceeding this is for nucleic acid molecules which code for a non-MAGE or non-BAGE tumor rejection antigen precursor (TRAP) which hybridize to a nucleic acid molecule containing the described nucleotide sequence of SEQ ID NO: 1, which is the sequence encoding the GAGE-1 TRAP.

7. Applicant is reminded of the Revised Interim Guidelines for the Examination of Patent Applications Under the 35 U.S.C. 112, ¶ 1 "Written Description" Requirement, Federal Register, Vol. 64, No. 244, pages 71427-71440, Tuesday December 21, 1999; the following rejection is set forth herein.

Claim 49 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention.

The specification does not provide adequate written description of the claimed invention. The legal standard for sufficiency of a patent's (or a specification's) written description is whether that description "reasonably conveys to the artisan that the inventor had possession at that time of the. . .claimed subject matter", Vas-Cath, Inc. V. Mahurkar, 19 USPQ2d 1111 (Fed. Cir. 1991). In the instant case, the specification does not convey to the artisan that the applicant had possession at the time of invention of the isolated nucleic acid molecule which encodes a GAGE tumor rejection antigen precursor, the complementary sequence of which hybridizes, at the conditions recited in claim 49.

The instant claim encompasses nucleic acid molecules that encode numerous undisclosed TRAPs. The "GAGE tumor rejection antigen precursor" of instant claim 49 encompasses molecules that partially or wholly derive from proteins encoded for by DNA molecules other than those that encode SEQ ID NO: 1 or other than those that encode GAGE-2 through GAGE-6, i.e., any sequence from any protein derived from a DNA molecule that hybridizes to it's own complement or presumably to a probe from SEQ ID NO: 1-6. There is insufficient disclosure in the specification on such nucleic acid molecules.

To fulfill the written description requirement, a patent specification must describe an invention and do so in sufficient detail that one skilled in the art can clearly conclude that "the inventor invented the claimed invention." Lockwood v. American Airlines, Inc., 107 F.3d 1565, 1572, 41 USPQ2d 1961, 1966 (1997); In re Gosteli , 872 F.2d 1008, 1012, 10 USPQ2d 1614, 1618 (Fed. Cir. 1989) (" [T]he description must clearly allow persons of ordinary skill in the art to recognize that [the inventor] invented what is claimed."). Thus, an applicant complies with the written description requirement "by describing the invention, with all its claimed limitations, not that which makes it obvious," and by using "such descriptive means as words, structures, figures, diagrams, formulas, etc., that set forth the claimed invention." Lockwood , 107 F.3d at 1572, 41 USPQ2d at 1966.

An adequate written description of a molecule "requires a precise definition, such as by structure, formula, chemical name, or physical properties," not a mere wish or plan for obtaining the claimed chemical invention. Fiers v. Revel , 984 F.2d 1164, 1171, 25 USPQ2d 1601, 1606 (Fed. Cir. 1993). Accordingly, "an adequate written description ... requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it; Id. at 1170, 25 USPQ2d at 1606.

The specification discloses that SEQ ID NO: 1 is the cDNA for GAGE-1, and that 5 other cDNAs which were identified using a GAGE-1 related molecular probe and "stringent" hybridization conditions are cDNA for GAGE-2 through GAGE-6 (page 11 at lines 19 and 20, paragraph spanning pages 19 and 20 and page 28 at lines 8-12). The disclosure is for nucleic acid molecules which code for a non-MAGE or non-BAGE tumor rejection antigen precursor (TRAP) which hybridize to a nucleic acid molecule containing the described nucleotide sequence of SEQ ID NO: 1, which is the sequence encoding the GAGE-1 TRAP.

In claims involving chemical materials, generic formulae usually indicate with specificity what the generic claims encompass. One skilled in the art can distinguish such a formula from others and can identify many of the species that the claims encompass. Accordingly, such a formula is normally an adequate description of the claimed genus. However, a generic statement such as "An isolated nucleic acid molecule which encodes a GAGE tumor rejection antigen precursor, the complementary sequence of which hybridizes" at stringent conditions recited in the instant claim 49, without more, is not an adequate written description of the genus because it does not distinguish the claimed genus from others. It does not specifically define any of the nucleic acid molecules that fall within its definition. It does not define any structural features commonly possessed by members of the genus that distinguish them from others. One skilled in the art therefore cannot, as one can do with a fully described genus, visualize or recognize the identity of the members of the genus. A definition by the property of encoding a "GAGE tumor rejection antigen precursor" the "complementary sequence of which hybridizes" under stringent conditions with its own sequence does not suffice to define the genus because it is only an indication of what the property the nucleic acid molecule has, i.e., of being some type of TRAP "GAGE" and of hybridizing to its complement, in this case its own complement. See Fiers, 984 F.2d at 1169-71, 25 USPQ2d at 1605-06. It is only a

definition of a useful result rather than a definition of what achieves that result. The description requirement of the patent statute requires a description of an invention, not an indication of a result that one might achieve if one made that invention. See In re Wilder, 736 F.2d 1516, 1521, 222 USPQ 369, 372-73 (Fed. Cir. 1984) (affirming rejection because the specification does "little more than outlin [e] goals appellants hope the claimed invention achieves and the problems the invention will hopefully ameliorate."). Accordingly, naming a type of material generally known to exist, in the absence of knowledge as to what that material consists of, is not a description of that material.

The instant disclosure of nucleic acid molecules encoding GAGE-1-6, i.e., SEQ ID NO: 14-18, does not adequately describe the scope of the claimed invention, which encompasses a substantial variety of subgenera. Since the disclosure fails to provide sufficient relevant identifying characteristics that identify members of the genus, and given the broad genus claimed, the disclosure of a few peptides of defined sequence is insufficient to describe the claimed genus.

8. The following is a quotation of the second paragraph of 35 U.S.C. 112:
The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 49 and 50 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

a. Claim 49 is indefinite in the recitation of "the complementary sequence of which hybridizes" in line 2 because it is not clear what is meant.

b. Claim 50 is indefinite in the recitation of "isolate" in line 1 because it is not clear what is meant. It is suggested that Applicant amend the said claim to recite "isolated" if that is what is meant.

9. For the purpose of prior art rejections, the filing date of the instant claims 49 and 50 is deemed to be the filing date of the parent application serial no. 5,858,689, i.e. 9/21/95, as the earlier filed parent applications do not support the claimed limitations of the instant application. The limitation "hybridizes...for 18 hours at 65" degrees C is not disclosed in the said earlier filed applications.

10. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

11. Claim 49 is rejected under 35 U.S.C. 102(a) as being anticipated by WO 95/03422 and admissions in the specification on page 11 at lines 19 and 20, paragraph spanning pages 19 and 20, and page 28 at lines 8-12).

WO 95/03422 teaches an isolated nucleic acid molecule which hybridizes under stringent conditions to GAGE-1 (SEQ ID NO: 1 of the reference) and codes for a TRAP that is not a MAGE or BAGE TRAP (especially claim 2 and page 12 at lines 1-25). WO 95/03422 teaches stringent conditions are hybridization in 1M NaCl, 1% SDS and 10% dextran sulfate, followed by two washes at room temperature for 5 minutes in 2XSSC, and one wash for 30 minutes in 2XSSC, 0.1% SDS.

The admissions in the specification at the said locations are that SEQ ID NO: 1 is the cDNA for GAGE-1 and that 5 other cDNAs were identified using a GAGE-1 related molecular probe (amino acid residues 20-328) and "stringent" hybridization conditions (recited in instant claim 49).

Although WO 95/03422 does not teach the hybridization and wash temperature is 65 degrees C, the claimed isolated nucleic acid molecule appears to be the same or similar to the isolated nucleic acid molecule of the prior art absent a showing of unobvious differences. Since the Patent Office does not have the facilities for examining and comparing the isolated nucleic acid of the instant invention to those of the prior art, the burden is on applicant to show an unobvious distinction between the isolated nucleic acid molecule of the instant invention and that of the prior art. See In re Best, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977).

12. SEQ ID NO: 14 appears to be free of the prior art.

13. Claims 41-48 are objected to as reciting SEQ ID NO, i.e., SEQ ID NO: 15-18, which correspond to isolated nucleic acid sequences of non-elected Groups II-V in the restriction requirement mailed 5/1/02, but would be allowable if rewritten to delete the limitations pertaining to non-elected Groups II-V, i.e., "SEQ ID NO: 15, 16, 17 or 18".

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Art Unit: 1644

14. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Marianne DiBrino whose telephone number is 703-308-0061. The examiner can normally be reached on Monday and Thursday from 11 AM to 5 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan, can be reached on (703) 308-3973. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.
Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Marianne DiBrino, Ph.D.
Patent Examiner
Group 1640
Technology Center 1600
April 10, 2003

CHRISTINA CHAN
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600

Notice of References Cited	Application/Control No. 09/782,745	Applicant(s)/Patent Under Reexamination BRUGGEN ET AL.	
	Examiner DiBrino Marianne	Art Unit 1644	Page 1 of 1

U.S. PATENT DOCUMENTS

*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Name	Classification
	A	US-			
	B	US-			
	C	US-			
	D	US-			
	E	US-			
	F	US-			
	G	US-			
	H	US-			
	I	US-			
	J	US-			
	K	US-			
	L	US-			
	M	US-			

FOREIGN PATENT DOCUMENTS

*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Country	Name	Classification
	N	WO 95/03422	02-1995	WO	Van Den Eynde, B. et al	—
	O					
	P					
	Q					
	R					
	S					
	T					

NON-PATENT DOCUMENTS

*		Include as applicable: Author, Title Date, Publisher, Edition or Volume, Pertinent Pages)
	U	
	V	
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	X	

*A copy of this reference is not being furnished with this Office action. (See MPEP § 707.05(a).)
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